

# **Potential Tobacco Product Violations Form**

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Office of Compliance and Enforcement, CTP  
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# Agenda

- Background
- Form 3779
- FDA Acknowledgment Letter
- FDA Follow-up
- Future
- Useful Links

# Background

- FDA's Center for Tobacco Products (CTP) is providing the public and other stakeholders with another option for reporting potential violations of the Tobacco Control Act and related regulations with the downloadable Potential Tobacco Product Violations Reporting form.
- By making it easier for everyone to report potential violations, FDA is able to better monitor compliance with the laws, help reduce the health burden of tobacco use on the American public, and protect the public health.

# Reporting Options

CTP provides the public and other stakeholders with various options to report potential violations of the Tobacco Control Act.

To report a potential violation, any interested party may:

- Call the Tobacco Call Center using CTP's toll-free number at 1-877-CTP-1373
- Email CTP at [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov)
- Send a letter to FDA Center for Tobacco Products c/o Document Control Center, 9200 Corporate Boulevard, Rockville, MD 20850-3229
- Use CTP's new PDF Form, the **Potential Tobacco Product Violations Reporting form (Form 3779)**

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# Form FDA 3779

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

## Potential Tobacco Product Violations Report

Form Approved: OMB No.: 0910-0716  
Expiration Date: 07/31/2014  
(See page 3 for PRA Statement)

### Directions:



Use this form to report potential tobacco-related violations of the Federal Food, Drug, and Cosmetic Act and associated regulations. These submissions are reviewed by FDA's Center for Tobacco Products.

**WHO** can report? - Any member of the public.

Tell us:

**WHEN** did you see the potential violation?

**WHERE** did the potential violation occur?

**WHAT** is the potential violation?

**WHY** report? - Information we receive from the public is often very helpful in identifying problems with marketed products and possible violations of the laws that we enforce.

To submit your report, complete the form below:

# Form FDA 3779

## Date and State Where Violation Occurred

Date potential violation occurred ( <i>mm/dd/yyyy</i> )	I do not recall the date this potential violation occurred <input type="checkbox"/>	State in which potential violation occurred
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## Description of Product

Type	Tobacco Brand
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### Potential violation type (choose all that apply)

- |  |   |
|--|---|
| <input type="checkbox"/> Sales to minors                 | <input type="checkbox"/> Vending machine/self-service display/direct access to cigarette or smokeless tobacco |
| <input type="checkbox"/> Flavored cigarette sales        | <input type="checkbox"/> Sale of cigarettes in packs of less than 20  |
| <input type="checkbox"/> Advertising/promotion/marketing | <input type="checkbox"/> Unsure   |
| <input type="checkbox"/> Free samples                    |   |

### Type of potentially violative promotional materials (choose all that apply)

- |  |  |
|--|--|
| <input type="checkbox"/> Newspaper               | <input type="checkbox"/> Price signage |
| <input type="checkbox"/> Magazine                | <input type="checkbox"/> Posters       |
| <input type="checkbox"/> Periodicals             | <input type="checkbox"/> Coupons       |
| <input type="checkbox"/> Billboard               | <input type="checkbox"/> Internet      |
| <input type="checkbox"/> Direct mail             | <input type="checkbox"/> Unsure        |
| <input type="checkbox"/> In-store advertisements |  |

### Who potentially violated? (choose all that apply)

- |                                       |                                      |
|---------------------------------------|--------------------------------------|
| <input type="checkbox"/> Retailer     | <input type="checkbox"/> Distributor |
| <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Unsure      |
| <input type="checkbox"/> Importer     |                                      |

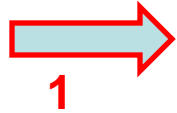
# Form FDA 3779

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## Potential Tobacco Product Violations Report

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Description of potential violation

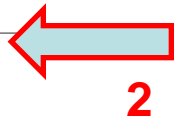


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## Name and physical address of the potential violator, if known

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Retailer, manufacturer, importer, or distributor name



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Street Address



# Form FDA 3779



**May we contact you if we  
need additional information?**

- ☐ No, I want my report to be anonymous. *(Please note that if you submit this form by email, FDA will receive your email address. However, if you choose "no" FDA will not contact you.)*
- ☐ Yes, FDA may contact me. *(Please fill in contact information below.)*

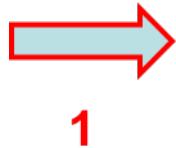
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Name

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Affiliation *(such as company, school, or group)*

# Form FDA 3779



**Please email me to notify me  
that FDA got my complaint**

☐ No  
☐ Yes

*In order to receive a response, please configure your email spam/junk  
filter to allow messages from [ctpcompliance@fda.hhs.gov](mailto:ctpcompliance@fda.hhs.gov). In most cases,  
this is solved by adding our email address to your address book.*

If you would rather submit your report to us in writing, along with any attachments,  
please do so at the the following address:

Potential Tobacco Products Violation Report, Office of Compliance and Enforcement  
FDA Center for Tobacco Products  
c/o Document Control Center  
9200 Corporate Boulevard  
Rockville, MD 20850-3229

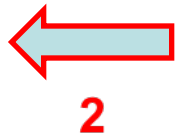
To reach us by telephone, please call 1-877-CTP-1373, and select option 3.  
You may also email us at [ctpcompliance@fda.hhs.gov](mailto:ctpcompliance@fda.hhs.gov).

Submit By Email

Print Form

Reset Form

An email message automatically will be produced when you click the SUBMIT BY EMAIL button. In the resulting email  
message, please don't forget to click the "Send" button or its equivalent when you are ready to send the email.



# FDA Acknowledgment Letter



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Center for Tobacco Products  
9200 Corporate Boulevard  
Rockville, MD 20850-3229

Name of Individual Submitting Form  
Title of Individual Submitting Form  
Street Address  
City, State, Zip

Tracking Number: 1111111

Dear Individual Submitting Form:

This is in response to your letter received on May 15, 2013 in which you provided information regarding a regulated tobacco product. In your correspondence you described an alleged violation.

Thank you for providing this information to the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP). We take such reports seriously, and we will evaluate this matter to determine what follow-up action, if any, is appropriate. The type and extent of any follow-up is dependent upon the nature of the problem and the possible impact on the public health.


While FDA does not provide information regarding ongoing investigations, information can be obtained pursuant to a Freedom of Information Act (FOIA) request once an investigation is closed. Written requests for information should reference the above tracking number and may be sent to the following address:

Food and Drug Administration  
Division of Freedom of Information  
Office of Shared Services  
Office of Public Information and Library Services  
12420 Parklawn Drive  
ELEM-1029  
Rockville, MD 20857

If you have any other information or additional questions, please contact CTP at [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov) or 1-877-CTP-1373.

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This is in response to your letter received on May 15, 2013 in which you provided information regarding a regulated tobacco product. In your correspondence you described an alleged violation.

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# FDA Follow-Up

- The information provided on the form is reviewed by FDA's Office of Compliance and Enforcement (OCE) at CTP
- OCE evaluates the report and determines what follow-up action, if any, is appropriate
- Reports submitted by the public and stakeholders may be helpful in identifying possible violations of the Tobacco Control Act and related regulations that FDA enforces
- OCE independently collects evidence of a violation before it initiates any enforcement action

# Future

In the future:

- FDA plans to make a web-based form available

# Useful Links

- The **Potential Tobacco Product Violations Reporting form (Form 3779)**  
<http://www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/ucm330160.htm>
- The FDA's **Center for Tobacco Products Homepage:**  
[www.fda.gov/tobaccoproducts](http://www.fda.gov/tobaccoproducts)
- The FDA's **FOIA Division Homepage:**  
<http://www.fda.gov/RegulatoryInformation/foi/default.htm>